Remarks/Arguments

I. Status of the Claims

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-98 are pending in the instant application.

Claims 22 and 50 are currently amended to remove the phrase "and/or" and substitute the phrase "or...or mixtures thereof. These phrases are believed to be equivalent, and the new language is believed to lack ambiguity.
Therefore, no new matter is interposed by these amendments.

II. Claims Rejected under 35 U.S.C. § 103(a)

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-98 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mizumoto et al., U.S. Patent No. 5,576,014, in view of Straub et al., U.S. 6,395,300.

As stated by the Examiner, Mizumoto does not expressly teach the claimed surfactant, as well as the claimed active agent such as celecoxib.

Straub is proffered as adding a wetting agent or surfactant into tablets, and celecoxib as an active agent.

Applicants disagree with this analysis. Straub deals with a completely different technology, forming a matrix containing an active agent. This matrix is formed by dissolving a drug in a volatile solvent, combining a pore-forming agent with the drug solution and removing the volatile solvent and pore-forming agent to yield a dry porous matrix. (see for example, column 2, lines 29-54 and claims) This method is said to be useful in drugs with low solubility, such as celecoxib. Applicants assert, however, that this method and the claimed method are completely different, and there is provided no motivation, either inherent or express, to combine the teachings of Mizumoto and Straub.

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-98 stand further rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mizumoto et al., U.S. Patent No. 5,576,014, in view of Straub et al., U.S. 6,395,300, and further inview of Jain et al., U.S. Patent No. 6,316,029.

Jain is asserted to provide a surfactant.

Applicants point out that Jain et al, in the Background of the Invention at column 2, lines 54-60, actually cites to Mizumoto et al. (described as a "Wowtab®), and

references the patent number U.S. Pat. No. 5,576,014, the same patent used to reject the instant application. Importantly, at column 3, lines 36-50 it is stated:

> None of the described prior art teaches a rapidly disintegrating or dissolving, or "fast melt," dosage form in which a poorly soluble active ingredient is in a nanoparticulate form. **This is significant because the prior art fast melt formulations do not address the problems associated with the bioavailability of poorly soluble drugs. While prior art fast melt dosage forms may provide rapid presentation of a drug, frequently there is an undesirable lag in the onset of therapeutic action because of the poor solubility and associated slow dissolution rate of the drug.** Thus, while prior art fast melt dosage forms may exhibit rapid disintegration of the drug carrier matrix, this does not result in rapid dissolution and absorption of the poorly soluble drug contained within the dosage form. (emphasis added)

Therefore, rather than providing additional motivation to combine references, Jain actually teaches away from the present invention by suggesting that the Mizumoto reference would not work with a poorly soluble active agent (such as celecoxib). In contrast, the present specification states:

> Processes of the present invention have been found to resolve at least some of the difficulties alluded to above **in a surprisingly effective manner**. Thus, in a significant advance in the art, a selective cyclooxygenase-2 inhibitory drug of low water solubility is now presented in a novel, easy-to-swallow, fast-melt formulation. A particular advantage of processes of the invention is that oral fast-melt tablets containing a cyclooxygenase-2 inhibitory drug of low water solubility, even such a drug having a relatively high dosage requirement, for example celecoxib, can be prepared by fluid bed granulation and compression. These oral fast-melt tablets provide a heretofore nonexistent dosage form of a selective cyclooxygenase-2 inhibitory drug that is efficient to produce, convenient and easy to swallow (emphasis added)

Thus, rather than render the instant invention obvious, the combination of Mizumoto, Straub and Jain effectively teach that the invention would not work. This cannot be viewed as rendering the claimed invention obvious. Therefore, it is respectfully requested that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

V. Conclusion

For all of the above reasons, reconsideration and withdrawal of the rejections 35 U.S.C. § 103(a) is respectfully requested, and allowance of claims is solicited.

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,

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